AMERICAN SOCIETY OF HEMATOLOGY

Conflict-of-Interest Policy

Revised October 2010

EXECUTIVE SUMMARY

The American Society of Hematology (ASH) is dedicated to advancing the specialty of hematology. To accomplish this mission, ASH provides support for a variety of activities in the areas of research, education, training, and advocacy. The integrity of ASH and the activities it undertakes depends on the avoidance of conflicts of interest, or even the appearance of conflicts, by the individuals involved with those activities.

ASH has adopted eight principles that underscore its commitment to managing real/perceived conflicts of interest, as well as eight policies that lay out specific ways in which the Society safeguards the integrity of the programs and activities in which its membership is engaged. This document constitutes the "ASH Conflict of Interest Policy."

I. Principles

<u>Principle 1</u>: The integrity of ASH and the scientific, educational, and advocacy activities it undertakes depend on the avoidance of bias arising from conflicts of interest, or from the appearance of such conflicts, by the individuals involved with those activities. Personal financial considerations must never be allowed to cloud physicians' and scientists' decisions on care of patients, safety of drugs or devices, or proper conduct of biomedical research. Continuing medical education (CME) provided to physicians by ASH must be free of bias devolving from financial arrangements or considerations.

<u>Principle 2</u>: A conflict of interest exists when an individual has material interests, regardless of value or dollar amount, outside of ASH that could influence or could be perceived as influencing his/her decisions, actions, or presentations. These interests, which include employment, consultancy, equity, research funding, honoraria, patents and royalties, speakers bureau involvement, advisory committee or board of directors membership, expert testimony, and financial support for the costs of travel to the ASH annual meeting, are relevant if they occurred in the past 24 months for the volunteer, partner, or spouse. Conflicts of commercial interest may involve either an agent or device as the subject in question or an agent or device that might be in competition with the subject in question.

<u>Principle 3</u>: The atmosphere ASH desires is one where people are comfortable asking questions relating to conflict of interest without feeling awkward or accusatorial and where recusing one's self from participation in discussions that might be perceived as constituting a conflict is the norm rather than the exception.

<u>Principle 4</u>: Having a member of ASH with a conflict of interest does not necessarily preclude participation in ASH activities. In fact, such external relationships may enhance the value of that member to the Society.

<u>Principle 5</u>: ASH subscribes to the view that research and development sponsored by the biomedical industry play an important role in biomedical research and that academic-industrial relationships have developed useful and life-saving products.

<u>Principle 6</u>: The mission of ASH does not include marketing of pharmaceutical or biomedical products. While opportunities do exist for purchase of space for commercial displays at the ASH annual meeting and while *Blood* sells advertising pages, the revenues generated are devoted to the support of the Society's mission. To this end, strong firewalls have been designed to insulate ASH from inappropriate commercial influence.

<u>Principle 7</u>: The ASH policies are congruent with the positions of the Accreditation Council for Continuing Medical Education (ACCME) that state: (a) commercial support for CME must be acknowledged, (b) no employees or staff consultants in the interested company can be involved in the development of the CME activities, and (c) attendees be encouraged to report on their perceptions of any possible bias.

<u>Principle 8</u>: The considerations of conflict of interest are relevant not only to clinical research but may extend to all phases of biomedical research, including pre-clinical research. In pre-clinical research, financial conflicts of interest are particularly apt to lead to bias if the work is "reasonably anticipated; (a) to be a component of an Investigational New Drug application (IND) submission or (b) to progress to research involving human subjects within the coming 12 months."

II. Policies

The requirements of ASH apply to all persons who:

- 1. Are employees of ASH;
- 2. Seek to make presentations at any ASH meeting or to submit material for any ASH publication; or
- 3. Serve on the Executive Committee or other committees, or otherwise serve in an official service capacity on behalf of the Society.

<u>Policy 1</u>: Some individuals serve as expert witnesses, officers, directors, or members of scientific advisory boards of companies, participate in company-sponsored speakers' bureaus, or accept subsidies for the costs of travel to the ASH annual meeting. All of these activities represent conflicts of interest.

<u>Policy 2</u>: ASH holds its members serving in governance positions to certain standards with regard to conflict of interest. Specifically, when an ASH member has a conflict, s/he will not:

- 1. Take any action on behalf of ASH concerning the subject in conflict or any issue relevant to the subject in conflict;
- 2. Participate in discussions on the subject without full disclosure;
- 3. Participate in decision-making discussions or cast a vote;
- 4. Imply that he/she is acting on behalf of ASH when discussing the relevant subject with third parties;

- 5. Fail to clarify with third parties with whom he/she deals on the relevant subject that he/she is not acting on behalf of ASH; or
- 6. Share confidential information, including disclosure of embargoed abstract data which would break laws relating to insider trading.

<u>Policy 3</u>: ASH has the right to take action regarding individuals who have exhibited biased behavior or action. These actions may include:

- 1. Requiring an individual to choose between the competing activities.
- 2. Prohibiting an individual from playing a decision-making role in ASH relevant to the conflict.
- 3. Prohibiting an individual from presenting at ASH-sponsored events.
- 4. Exclusion from publishing in *Blood* or other ASH publications.
- 5. Exclusion from participating in ASH committees.
- 6. Revocation of membership in ASH.

<u>Policy 4</u>: No donor, commercial or otherwise, can select speakers or awardees or be involved in the production of educational and/or scientific content.

<u>Policy 5</u>: Commercial support for CME must be acknowledged and no employees or staff consultants of the interested company can be involved in the development of the content of CME of ASH. Meeting attendees are provided with a formal opportunity to report on their perceptions of any possible bias in their review of the sessions for CME credit.

<u>Policy 6</u>: ASH considers certain clearly defined types of academic consulting and fees exempt from its definition of reportable financial interests, e.g., fees received for serving on grant application review groups (study sections) and fees given as honoraria (less than \$2,500 per event) by another academic institution for an academic activity, such as seminars and grand rounds.

<u>Policy 7</u>: Special precautions are taken to safeguard against a potential conflict of interest with regard to the Clinical Research Training Institute, which is targeted at helping trainees (fellows and junior faculty) who are early in their careers and wish to obtain the skills needed to design and conduct studies involving human subjects. More specifically, there are no corporate exhibits or handouts, no corporate contributions have been sought for funding, and it is the firm position of ASH that none will be solicited at any time in the future. From time to time, speakers who work for a pharmaceutical company are included as faculty because of their knowledge of the drug development process. These individuals are chosen solely for their knowledge of the subject matter, and they do not make promotional presentations of any kind at the Clinical Research Training Institute.

<u>Policy 8</u>: From time to time, ASH will sponsor an activity designed to develop evidence-based clinical guidelines. Special precautions are taken to safeguard against conflicts-of-interest with regard to the membership of evidence-based clinical guideline writing panels. Specifically, the need

to include scientists or physicians who are most knowledgeable about the subject will be balanced with the desire to have a conflict-free panel. At no time will a chair, co-chair, or compliance officer of a writing panel be accepted who has a financial relationship with a company whose drugs or devices might be affected by the guideline. Further, any potential conflicts will be vetted by the panel's compliance officer who must be conflict-free. The majority of the guideline panel must also be conflict-free.

The guideline writing panel will gather data from a wide variety of sources, including the relevant company and scientists or physicians who are actively working with that company. This is critical because the guideline writing panel will need input from those most knowledgeable about the subject. The guideline writing panel will then apply evidence tests to the information gathered to determine how much it can be relied upon in formulating the guideline. As is the case with all ASH committees, the guideline writing panel will have a Conflict of Interest Compliance Officer assigned who will monitor any potential conflicts of interest that could influence the guideline.

III. Process

Appropriate disclosure forms must be completed by anyone involved in ASH activities – committee members, annual meeting organizers and speakers, program planners for CME programs, and/or anyone involved in *Blood* and other ASH publications. As an ACCME-approved provider, ASH fully complies with the CME rules regarding meeting program design and speaker disclosure. ASH continues to separate corporate-sponsored symposia from the official ASH annual meeting and now prohibits anyone who participates in a corporate program from being invited as an ASH speaker in the same year. ASH has put enforcement mechanisms in place to ensure that oral and poster presentations fully disclose conflicts of interest; ASH has also increased the number of hematologists who formally review educational and special speaker presentations – as well as corporate-sponsored symposia – for any bias or the appearance thereof. A centralized system tracks speakers who fail to comply with conflict of interest requirements; the system is being expanded to allow Web-based management of the process.

ASH policies apply generally to all types of conflicts, not just financial. More often, the bias of conflicts are institutional and personal ties that must be managed in ASH committee meetings and study sections.

Questions and comments regarding the ASH conflict of interest principles and policies can be directed to the ASH Chief Operating Officer, Matthew Gertzog at mgertzog@hematology.org.